UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/429,832	10/29/1999	RAMESH A. BHAT	0646/1D205-U	6371

32801 7590 04/21/2003

DARBY & DARBY P.C.
P.O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER
BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
1646	16

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/429,832	Applicant(s) Bhat et al
	Examiner Nirmal S. Basi	Art Unit 1646

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Jan 17, 2003*.

2a) X This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *17-41* is/are pending in the application.

4a) Of the above, claim(s) *19-27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *17, 18, and 28-41* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
4) ☐ Interview Summary (PTO-413) Paper No(s).
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The response to the office action filed 1/17/03 (paper number 15) has been entered. The response to the office action filed 1/8/02 (paper number 13) has been entered. Amendment filed 8/22/01 (paper number 9) has been entered. Applicant added new claims 28-41 in paper number 13. Claims 28-31 are drawn to the elected polypeptide elected polypeptide of Group I and will be examined. Applicant has requested the rejoining of withdrawn claims 19-27. The request to rejoin under practice in accordance with MPEP 821.04 must be submitted upon the indication of the allowability of the product claims. Accordingly, claims 19-27 remain withdrawn from consideration as being directed to a non-elected invention.

Response to Applicants Arguments

2. The rejection of claim 17 and 18 under 35 USC, second paragraph are withdrawn in view of applicants arguments and amendments filed in paper numbers 15 and 9.

3. Amended claim 18 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. The rejection of claim 18 is the same as disclosed in paper number 8 (5/22/01). Applicants arguments are addressed below.

The claim is drawn to purified polypeptide:

a) comprising amino acids 1-45 of the sequence depicted in SEQ ID NO:2.

Applicants argue amino acids 1-45 of SEQ ID NO:2 is a novel domain of human estrogen receptor-β, specifically described in the application as filed, and one of skill in the art would readily understand an estrogen receptor having such a sequence. Applicant argues any function is intrinsic to the claimed estrogen receptor β and that the domain of amino acids 1-45 of SEQ ID NO:2 imparted functionality to the protein of hERBl as demonstrated by the attenuation of IL-1β mediated NFkB transcription activation. Applicants arguments have been fully considered but not found persuasive. The specification, page 13, lines 1-13, discloses $hER\beta_T$ (truncated) caused a 2-fold stimulation of ERE activity, by contrast, $hER\beta_L$ (full length) caused a 6 fold stimulation of ERE activity, $hER\beta_L$ was capable of attenuating the IL-1β mediated NFkB transcription activation while $hER\beta_T$ exhibited no inhibitory activity. The claims do not recite the intrinsic function provided by amino acids 1-45 of SEQ ID NO:2. Both the truncated form and full length form of the receptor are capable of stimulating ERE activity. The critical feature of the invention provided by amino acids 1-45 to the estrogen receptor-β is not stated in the claims. Therefore instant disclosure of a single distinct polypeptide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, mutated, variant and fusion proteins with undefined intrinsic activity or critical feature of the invention.

4. Newly added claims 31-33, 36-37 and 40-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claim is drawn to purified polypeptide:

a) comprising amino acids 1-45 of the sequence depicted in SEQ ID NO:2 wherein said polypeptide is chemically synthesized or modified with a label capable of providing a detectable signal.

The specification, page 13, lines 1-13, discloses $hER\beta_T$ (truncated) caused a 2-fold stimulation of ERE activity, by contrast, $hER\beta_L$ (full length) caused a 6 fold stimulation of ERE activity, $hER\beta_L$ was capable of attenuating the IL-1β mediated NFkB transcription activation while $hER\beta_T$ exhibited no inhibitory activity. The claims do not recite the intrinsic function provided by amino acids 1-45 of SEQ ID NO:2. Both the truncated form and full length form of the receptor are capable of stimulating ERE activity. The critical feature of the invention provided by amino acids 1-45 to the estrogen receptor-β is not stated in the claims. Therefore instant disclosure of a single distinct polypeptide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, mutated, variant and fusion proteins with undefined intrinsic activity or critical feature of the invention. The specification discloses an isolated cDNA sequence, SEQ ID NO: 1 which encodes the polypeptide depicted in SEQ ID NO:2. The instant disclosure of a single distinct polypeptide does not adequately

describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, mutated, variant and fusion proteins. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by an amino acid sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information the peptide comprising amino acids 1-45, such as definitive structural features of the claimed genus of polypeptides and the claim fails to disclose the functional features of the claimed genus of polypeptides. The common function of peptide comprising amino acids 1-45, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description, however, of the sites at which variability may be tolerated, which amino acids are to be substituted to produce intrinsically active polypeptide. There is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to make, isolate , identify and use the claimed polypeptide comprising amino acids 1-45 of SEQ ID NO:2 encompassed without undue experimentation.

An adequate written description of a protein, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of a protein is more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the protein itself. Accordingly, the specification does not provide a written description of the invention of claim 18, 31-33, 36-37 and 40-41

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
April 18, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER